Does methadone maintenance treatment based on the new national guidelines work in a primary care setting?

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SUMMARY

Background: *General practitioners (GPs) are being encouraged to treat more drug users but there are few studies to demonstrate the effectiveness of primary care treatment.*

Aim: *To determine whether patients retained on methadone maintenance treatment for one year in a modern British primary care setting, with prescribing protocols based on the new national guidelines, can achieve similar harm reduction outcomes to those demonstrated in other settings, using objective outcome measures where available.*

Design of study: *Longitudinal cohort study.*

Setting: *The Primary Care Clinic for Drug Dependence, Sheffield.*

Method: *The intervention consisted of a methadone maintenance treatment provided by GPs with prescribing protocols based on the 1999 national guidelines. The first 96 eligible consenting patients entering treatment were recruited; 65 completed the study. Outcome measures were current drug use, HIV risk-taking behaviour, social functioning, criminal activity, and mental and physical health, supplemented by urinalysis and criminal record data.*

Results: *Frequency of heroin use was reduced from a mean of 3.02 episodes per day (standard deviation [SD] = 1.73) to a mean of 0.22 episodes per day (SD = 0.54), (χ^2 = 79.48, degrees of freedom [df] = 2,* P*<0.001), confirmed by urinalysis. Mean numbers of convictions and cautions were reduced by 62% (z = 3.378,* P*<0.001) for all crime. HIV risk-taking behaviour, social functioning, and physical and psychological wellbeing all showed significant improvements.*

Conclusion: *Patients retained on methadone maintenance treatment for one year in a primary care setting can achieve improvements on a range of harm reduction outcomes similar to those shown by studies in other, often more highly structured programmes.*

Keywords: *heroin; addiction; methadone maintenance treatment; primary care.*

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Introduction

OVER the past 35 years, studies carried out in a number of different countries and settings have shown improved outcomes for patients addicted to heroin when treated with the replacement drug methadone on a maintenance basis.[1-3] In accordance with the developing harm reduction philosophy, outcomes measured have focused on illicit drug use and injecting behaviour, criminal activity, and physical and mental health. In all these areas methadone maintenance treatment has been consistently shown to be effective.

Recent developments in government policy[4-6] and the 1999 Department of Health guidelines for the treatment of drug dependence[7,8] have encouraged the development of primary care treatment for drug users. This has led to a nationwide expansion in primary care treatment for drug users, in a variety of service frameworks including traditional general practice, shared care schemes, and general practitioner (GP) led clinics. It has been pointed out, however, that the vast majority of available evidence on effectiveness relates to studies carried out in very different settings from any of those existing within modern British primary care.[9] Most studies have been carried out in secondary care settings and many studies involve treatment programmes relying on highly structured models of intervention, rather than the pragmatic substitution model, which is now dominant in the United Kingdom (UK).[10] This has led some commentators[11] to question the validity of extrapolating the existing evidence for methadone maintenance treatment to new and unstudied settings. Other commentators[12] have pointed out the need to look more closely at factors influencing differences in outcome between different methadone programmes. Although some evidence is available as to the effectiveness of methadone maintenance in primary care in the UK,[13-15] these studies have reflected services where methadone maintenance treatment is based on pre-1999 protocols, and sometimes includes shared care with secondary services. These studies have, furthermore, relied mainly on self-reported outcome data, including the assessment of illicit drug use and criminal activity.

This study investigates the effects of methadone maintenance treatment on patients starting treatment and retained for one year in the primary care clinic for drug dependence in Sheffield, using prescribing protocols modelled on the 1999 national guidelines. Outcomes are measured using urinalysis and criminal record data in addition to self-reporting.

HOW THIS FITS IN

What do we know?

Methadone maintenance treatment has been shown in a number of studies to reduce illicit drug use, crime, and risk-taking behaviour among heroin users, and to improve mental and physical health. Most of these studies were, however, carried out in highly structured programmes very unlike the modern pragmatic model of methadone prescribing that is current in the United Kingdom, and many of them rely heavily on self-reported data.

What does this paper add?

This study uses urinalysis and criminal record data to supplement self-reporting in a UK primary care setting with prescribing protocols based on the 1999 national guidelines. It shows that, in this setting and using objective outcome data, methadone maintenance treatment is effective in reducing illicit drug use, reducing crime, and producing improvements on a range of harm reduction outcomes.

Method

Setting

In Sheffield prior to 1999, in common with many other areas,[16,17] there was a very low level of interest among GPs in undertaking work with drug users. In order to break through this barrier, a primary care clinic was set up in 1999, led by GPs with a special interest (Box 1) and supported by a city-wide pharmacy scheme to dispense methadone with or without supervision. The main target group for the new service was the existing waiting list of long-term heroin users, some of whom had been referred more than two years previously to the overstretched consultant-led secondary care service in the city.

The new clinic opened in April 1999, shortly after the launch of the new national guidelines for the treatment of drug dependence.[7] These guidelines and the associated research evidence were used as the basis of the clinical protocols for the clinic[18-26] (Box 2).

In accordance with the primary care emphasis of the clinic, after an initial nursing assessment patients received 'case working' almost exclusively through their 10-minute doctor consultations. On the other hand, a well-developed pharmacy scheme was available to support the clinic so that doses of methadone could be dispensed under daily supervision with a system of reporting back missed doses and other problems to the prescriber.

Study design

This study employed a longitudinal design. The cohort was followed up for one year and interviewed at baseline, three months, and 12 months.

Ethics

The study was approved by the South Sheffield Research Ethics Committee.

Structure

- Led by GPs with a special interest (now 1.5 working time equivalents [WTE])
- Now has over 450 patients
- One full-time nurse specialist at time of study; now two
- Manager and administrative support
- Dedicated premises
- Deputising arrangements: costs of drugs prescribed met by GMS GPs
- Supported by city-wide pharmacy scheme for supervised methadone dispensing

Aims

- To provide evidence-based treatment for heroin users in a primary care setting
- To eliminate waiting lists and reduce pressure on secondary care services
- To encourage local GPs to treat drug users
- To encourage long-term treatment for patients of GPs not wishing to prescribe
- To encourage support and short-term prescribing where necessary for patients of GPs who do prescribe
- To provide clinical governance structure for primary care services

Box 1. The Sheffield primary care clinic.

- Widespread use of supervised dispensing
- Prescribing within licensed indications of medication
- Avoidance of benzodiazepine prescribing
- No tablets or injectables prescribed
- Emphasis on retention in treatment[18,19]
- Adequate doses of methadone prescribed[20-23]
- Harm reduction rather than abstinence-based approach[24-26]

Box 2. Clinical protocols.

Participants

Following a pilot study of patients retained in a general practice setting,[27] it was estimated that approximately 50 cases would be adequate to demonstrate a treatment effect. Anticipating a drop-out rate of up to 50%,[1] which has been demonstrated in other recent research,[13,28] it was decided to recruit approximately the first 100 consenting patients entering treatment from the waiting list. To be eligible for inclusion in the study, participants were required to be over 18 years of age, addicted to heroin, with no existing co-morbid psychiatric diagnosis, no concurrent serious physical illness, not pregnant, with no contraindications to methadone, and not currently in methadone treatment. Addiction to heroin was established by a nurse specialist during assessment and was confirmed by drug-using history, clinical examination, and urinalysis. No patient who met the inclusion criteria refused to participate. Ninety-six patients were finally recruited to the study.

Measures

United Kingdom modified Opiate Treatment Index. The Opiate Treatment Index assesses current drug use, HIV risk-taking behaviour, social functioning, criminality, and health and psychological wellbeing, using an interviewer-administered questionnaire.[29] The version used for this study has been modified and validated for use in the UK.[30]

Objective measures. In addition to the self-reported outcomes measured by the Opiate Treatment Index, urinalysis results were collected to show illicit drug use, and criminal records were identified. Convictions and cautions in the 12-month period prior to entry into treatment were compared with those for the first 12 months in treatment. Crimes were broken down into categories: acquisitive crimes (crimes such as shoplifting, burglary, fraud), drug-related crimes (such as possession or dealing), and other crimes (typically driving offences or failure to attend court).

Interview procedure

Participants were interviewed on a total of three occasions to coincide with their routine clinic appointments. The first interview took place before treatment started. The next interview took place three months after the start of treatment and the final interview was then carried out after 12 months in treatment. All interviews were conducted by a team of researchers who were trained to apply standardised interview techniques.[31]

Data collection procedure

Results of urine tests were extracted from clinical records and in each case the sample provided on the actual date or within two weeks of the interview was used for analysis. Information on convictions and cautions was extracted from the criminal records of participants provided by South Yorkshire Police.

Results

Ninety-six eligible patients were recruited to the study and entered treatment. Eighty-four were still in treatment at three months and 81 completed three-month interviews. Of these, 68 were still in treatment at 12 months, of whom 65 completed the final interview. Twenty-five participants left the study after dropping out of treatment; of these, 13 were discharged from the clinic after failing to attend appointments, two went to prison, two moved away, two were discharged for poor compliance, and six were discharged drug-free. A further six patients were lost to the study after being repeatedly missed by the researcher when they came to the clinic for their appointments. There were no statistically significant differences between those who dropped out of treatment and those who remained in treatment for one year in terms of demographic characteristics or baseline measures.

Sample characteristics

The final cohort comprised 65 participants, 82% of whom were male, with a mean age at study intake of 28 years (SD [standard deviation] = 6 years). The majority of participants were white (97%), single (60%), and unemployed (85%). Fifty-four per cent had previously spent some time in prison, with 23% having spent longer than one year in custody. Mean age at first daily heroin use was 20 years (SD = 4 years) with a mean number of years of using heroin of 10 (SD = 6 years).

Drug use outcomes

Heroin. Substantial reductions in the frequency of heroin use were seen with respect to both the self-reported scores and urinalysis results (Table 1). Over the 12-month period a highly significant reduction was seen in the number of heroin use episodes per day, from 3.02 (SD = 1.73) to 0.22 (SD = 0.54) (Friedman χ^2_r = 79.48, df [degrees of freedom] = 2, $P<0.001$).

Other drugs. Similar improvements were also seen in the self-reported use of cocaine, benzodiazepines and other illicit opiates (Table 1), although despite reasonable concordance, the proportion of positive urinalysis tests for cocaine and benzodiazepines did not change significantly.

Crime

Convictions and cautions (from criminal records). In the 12 months prior to the commencement of treatment the mean number of convictions and cautions received by the cohort was 3.14. This fell by 62% to 1.21 for the year post-treatment. Convictions and cautions for acquisitive crime fell by 69%, from 1.69 per year to 0.52 per year; those for drug-related crime fell by 83% and those for other crime (such as driving offences) fell by 33%. With the exception of 'other crime', all reductions were statistically significant (Figure 1).

Criminal activity (self-reported). Only property crime was disclosed as being committed at a level high enough for subsequent analysis. Forty-nine per cent of the cohort admitted to carrying out a property crime in the month preceding the initial interview, falling to 10% at three months and 5% after one year (Cochrane's Q = 36.64, df = 2, $P<0.001$).

Other outcomes

HIV risk-taking behaviour and social functioning. Significant improvements in overall HIV risk-taking behaviour were observed (Table 2). The improvement in risk-taking behaviour was owing to improvements in injecting drug use (Friedman χ^2_r = 48.92, df = 2, $P<0.001$) rather than sexual behaviour, which did not change. At the baseline interview 80% of the cohort had injected one or more drugs in the previous month, falling to 43% after three months and 36% after one year in treatment (Friedman χ^2_r = 63.24, df = 2, $P<0.001$).

Social functioning. Similar improvements were seen with respect to social functioning (Table 2). Sixty-two per cent of the cohort reported that more than half of their associates were illicit drug users at intake, falling to 21% at three months and 12% at one year.

Physical and psychological (GHQ-28) wellbeing. Six of the eight physical health categories of the Opiate Treatment Index showed significant reductions in morbidity (Table 3). Overall, physical health showed a 46% improvement at both three and 12 months. Significant differences were also observed for all GHQ-28 subsections, with anxiety, depression, social dysfunction, and somatic symptoms all improving substantially.

Table 1. Mean drug use scores (standard deviation) and urinalysis results at baseline, three months, and one year after treatment.

Substance	Mean number of drug use episodes per day in the month prior to:			
	Baseline (SD)	Three months (SD)	12 months (SD)	Significance level (*P*-value)
Heroin	3.02 (1.73)	0.32 (0.76)	0.22 (0.54)	<0.001
Other opiates (illicit)	0.72 (1.12)	-	0.04 (0.18)	<0.001
Cocaine	0.27 (0.97)	0.080 (0.35)	0.16 (0.73)	0.001
Alcohol[a]	0.23 (0.72)	0.71 (2.0)	2.20 (5.74)	0.001
Benzodiazepines	1.84 (3.7)	0.29 (0.93)	0.62 (2.04)	<0.001
Polydrug use score[b]	4.24 (1.19)	2.92 (1.37)	3.10 (1.57)	<0.001
Urinalysis results[c] (%)				
Opiates (not methadone) (positive)	95.3	59.4	50.8	<0.001
Cocaine (positive)	25.0	25.0	27.1	0.951
Benzodiazepines (positive)	42.2	32.8	30.5	0.229

[a]Mean number of units/week consumed in month prior to interview. [b]Polydrug use score is a composite score indicating the number of different classes of drug that the participant has used in the previous month. It is provided by the summation of all drug classes in which at least one drug usage episode was recorded for the previous month (minimum = 0 maximum = 11). [c]Concordance between self-reported drug use and urinalysis was calculated by converting the Opiate Treatment Index drug use scores to dichotomous variables (any drug use in previous month). Overall concordance was 86% for heroin, 82% for cocaine, and 71% for benzodiazepines. Cohen's κ statistic for each concordance pair was significant at either the 5% level or beyond in all cases.

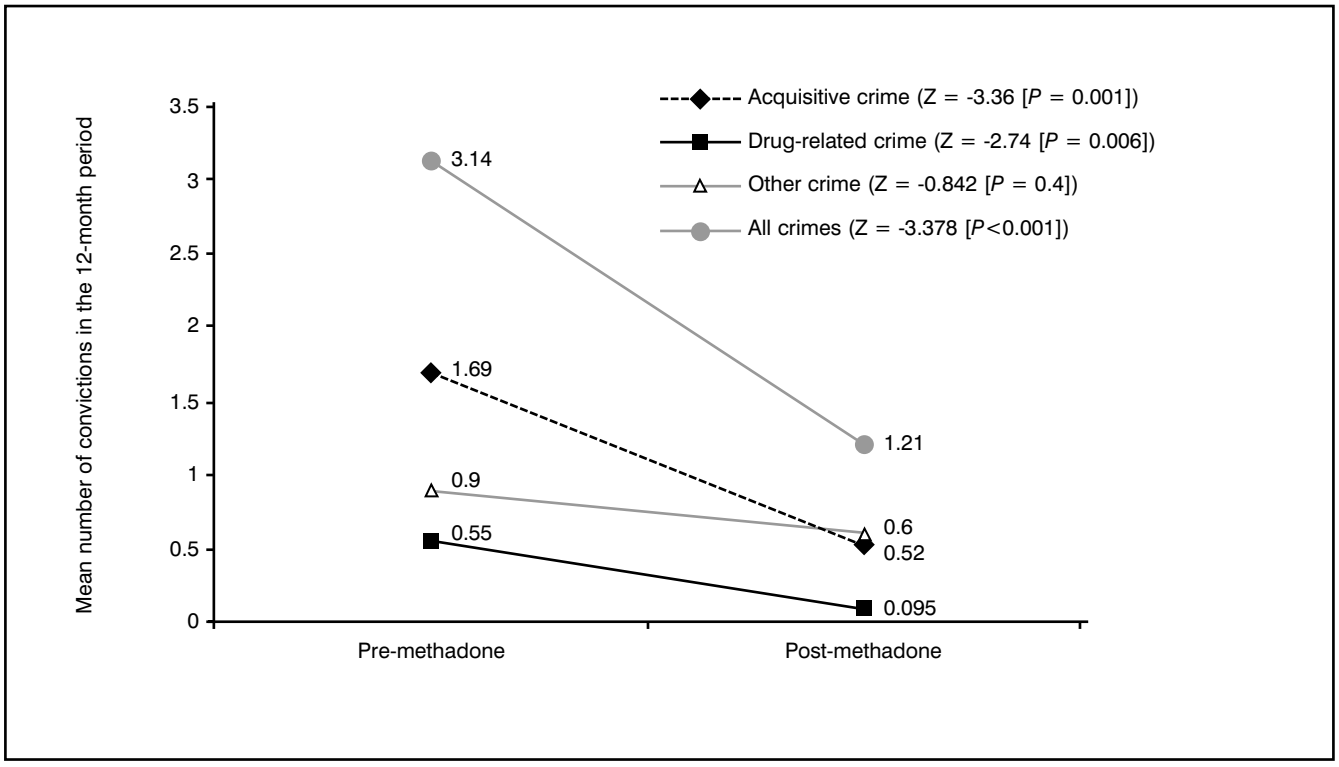

Figure 1. Mean number of convictions and cautions in the period 12 months prior to the start of methadone treatment and 12 months after treatment.

Discussion

These results confirm that methadone maintenance treatment, when prescribed in accordance with the 1999 national guidelines, is associated with highly significant improvements in illicit drug use, risk-taking behaviour, crime, and physical and mental health, and that this can be achieved in a primary care clinic setting. Outcomes based on self-reporting are substantiated in this study with urinalysis and criminal record data.

This study looks at the early stages of development of a GP-led service providing methadone maintenance treatment for heroin users. Ideally, services might provide a range of counselling and support services for patients and elements of shared care with other services, but in the early days of the Sheffield service none of these options were available on a regular basis and the study therefore looks almost exclusively at the effects of methadone treatment itself.

The most striking thing about the results is that, in spite of the relative lack of support services and case working, experienced GPs prescribing methadone on a harm reduction basis and with the support of a well organised pharmacy

Table 2. HIV risk-taking behaviour and social functioning subscale scores.

	HIV risk-taking behaviour scale (HRBS)			
	Baseline	Three months	12 months	Statistical tests (*P*-value)
HRBS				
Total score,[a] mean (SD)	9.98 (6.84)	5.20 (5.15)	5.50 (5.17)	<0.001
Drug use, mean (SD)	6.47 (5.52)	1.90 (3.14)	1.47 (3.24)	<0.001
Sexual activity, mean (SD)	3.52 (4.28)	3.30 (4.39)	4.03 (3.89)	0.320
Number of times injected drugs within the last month, *n* (%)				
None	13 (20)	35 (57)	41 (64)	<0.001
Less than once a day	9 (14)	23 (38)	17 (27)	
More than once a day	42 (66)	3 (5)	6 (9)	
Social functioning				
Social functioning score,[c] mean (SD)	23.48 (7.19)	17.40 (6.24)	16.00 (6.18)	<0.001
Proportion of associates who are illicit drug users *n* (%)				
None	12 (19)	32 (52)	41 (64)	<0.001
Less than half	12 (19)	17 (27)	15 (23)	
More than half	39 (62)	13 (21)	8 (12)	

[a]The HRBS is a composite scale of 11 questions that comprises two separate subscales (intravenous drug use and sexual activity). The range is from 0 to 55, where 0 is better. [b]Social functioning score is a composite score of 12 questions in three areas — employment, residential stability, and interpersonal conflict. The range is from 0 to 48 where 0 is better.

Table 3. Mean physical and psychological wellbeing scores.

	Baseline (SD)	Three months (SD)	12 months (SD)	Significance level (*P*-value)
Mean physical health scores				
General health	6.83 (2.41)	4.02 (2.51)	3.72 (2.40)	<0.01
Genitourinary	0.67 (0.67)	0.57 (0.59)	0.47 (0.54)	NS (>0.05)
Gynaecological (*n* = 12)	0.67 (0.49)	0.67 (0.65)	0.42 (0.51)	NS (>0.05)
Cardiorespiratory	4.17 (2.49)	2.47 (2.05)	2.42 (2.16)	<0.01
Injection-related	1.42 (1.27)	0.42 (0.79)	0.52 (0.87)	<0.01
Musculoskeletal	1.30 (0.89)	0.65 (0.84)	0.68 (0.75)	<0.01
Neurological	3.60 (2.30)	2.03 (2.08)	2.47 (2.13)	<0.01
Gastrointestinal	3.18 (1.51)	1.38 (1.33)	1.33 (1.22)	<0.01
Total health score[a]	21.30 (7.89)	11.67 (7.57)	11.68 (7.16)	<0.01
GHQ-28				
Anxiety	4.13 (2.37)	2.06 (2.30)	2.51 (2.47)	<0.01
Depression	3.38 (2.66)	1.02 (1.85)	1.23 (2.12)	<0.01
Social dysfunction	3.43 (2.22)	1.15 (1.88)	1.55 (2.02)	<0.01
Somatic symptoms	3.28 (2.17)	1.55 (2.00)	1.81 (2.09)	<0.01
Total score[b]	14.21 (7.77)	5.79 (7.10)	7.11 (7.56)	<0.001

[a]The physical health scale is produced from a checklist of symptoms related to the eight categories. The total score is given by the summation of all present symptoms. The range is 0 to 52 where 0 is better. [b]The GHQ-28 total score is produced by the summation of each of the four subscales. The range is from 0 to 28 where 0 is better. NS = not significant.

scheme, were able to produce significant harm reduction outcomes for patients retained within the programme.

As is the case with other recent studies in the field, randomisation of participants to a control group could not be considered ethically acceptable. The study of a cohort with repeated measures has for this reason been widely used in studies of this kind.[13,15]

The focus of this study is on the harm reduction effect of long-term maintenance treatment and outcomes for the cohort who succeeded in remaining in treatment. Those who dropped out of treatment were therefore not followed up, although it is notable that the attrition rates were in fact unusually low (see below) and a number of patients left treatment because they were drug-free.

The harm reduction outcomes demonstrated in this study reflect those found in different primary care settings by the National Treatment Outcomes Study (NTORS)[15,28] and the Glasgow scheme[13]; and in outcome studies in a variety of other, non-primary care settings.[1-3,10,18] This may lend weight to the suggestion that the core element of such programmes, the methadone treatment itself, is a major determinant in harm reduction irrespective of other elements of treatment. It has been noted by other commentators[32] that, as in this study, many of the major improvements seen in methadone maintenance treatment become apparent as early as three months into treatment.

Analysis of actual criminal records has very rarely been used as an outcome measure and to our knowledge this is

first time that it has been used in this setting. The results are especially striking in that they derive from criminal record data rather than self-reporting. Reductions in criminal activity of this magnitude are hugely significant to the individual in terms of quality of life, but also for families in terms of reduced imprisonment[27] and in reductions in social and economic costs to society at large.[33]

A similarly impressive improvement was observed with regard to the numbers of patients shown by urinalysis to be using illicit opiates, which fell from 95.3% at baseline to 50.8% at 12 months. There is in fact a high degree of concordance in our study between urine results and self-reporting, as was noted by the NTORS researchers.[28] The relatively less impressive impact on other drug use, including cocaine, and on high-risk sexual behaviours as opposed to drug-related risk behaviours, mirrors that discussed by other commentators.[10]

About 70% of patients who entered treatment completed 12 months in treatment. These levels of drop-out are low compared with those reported by other researchers,[1,3,28] which may reflect the emphasis on retaining patients in treatment and determination to prescribe adequate dosages of methadone in the primary care clinic. This does not suggest that the emphasis placed on supervised dispensing by the new national guidelines has a major deterrent effect for patients. Seivewright[9] points out that some strict programme cohorts may be self-selecting according to ability to adhere solely to methadone; this is not the case in the current study because in accordance with the harm reduction emphasis of the clinic, patients were not expelled purely for illicit drug use.

In their 1999 review of maintenance treatment in opioid dependence, Ward, Hall and Mattick conclude that 'the major challenge in reducing the public health burden of opioid dependence is to deliver safe and effective maintenance treatment to as many people as can benefit from it'.[1] They go on to recommend a community-based approach to maintenance treatment such as the model where GPs prescribe methadone and it is dispensed by community pharmacies, as in this study. However, they also make the point that new models for delivering maintenance treatment need to be the subject of research in order to demonstrate that the effectiveness of the traditional treatment model has not been lost. This study suggests that, in a primary care clinic setting, methadone maintenance treatment is indeed effective.

Conclusion

The primary care clinic that forms the setting for this study is part of a heterogeneous nationwide development of primary care-led schemes. It is not necessarily representative of the type of practice used by all GPs, and many primary care-led programmes now offer more shared care or psychosocial support, but it does represent one example of the modern, pragmatic approach to methadone prescribing undertaken in many UK primary care settings. The outcomes of this study support the view that GP-led schemes can deliver the harm reduction outcomes reported in studies of other, often more highly structured settings.

We can conclude that for heroin-addicted patients who are retained in methadone maintenance treatment in a primary care setting of this kind, with protocols based on the 1999 national guidelines, there is a likelihood of achieving very significant improvements on a range of outcomes, many of which affect the wider society as well as drug users themselves.

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